Roethig, Hans

From: Roethig, Hans-Juergen
Sent: Wednesday, March 14, 2001 2:48 PM
To: Walk, Roger A.
Subject: Ethical rules for ERP funding

Dear Roger,
Despite the fact I did not yet talk to Max Eisenberg I like to give you my thoughts for the rules. Some of them are optional or definitely need discussion. In general the FDA rules are based on a lot of practical experience, so I think that makes them recommendable.
All clinical research in humans has to comply with:
CFR 50 (Informed Consent), CFR 54 (Financial Disclosure), CFR 56 (IRB);
part 312 of the IND regulations, subpart D (Investigators obligations):
Any additional investigator's state or institutional regulation;
ICH guideline for Good Clinical Practice;
Declaration of Helsinki;
PM/tobacco specific I would add:
No research with tobacco in minors, pregnant or lactating women, institutionalized subjects, or smoking promotion will be funded.
Best regards
Hans